distinct genes" and "the number of combinations claimed is $73!=4.5\times10^{105}$." Applicants respectfully traverse the restriction requirement for the following reasons.

I. Improper restriction of the different groups of claims

Applicants first traverse the restriction among the 10 different groups of claims set forth in the restriction requirement. According to the MPEP, there are two criteria for a proper Restriction Requirement: (1) the inventions must be independent or distinct as claimed, and (2) there must be a serious burden on the Examiner if restriction is not required (MPEP § 803). If two or more subjects are related rather than independent, they are deemed "distinct" only if they "are capable of separate manufacture, use, or sale as claimed, AND ARE PATENTABLE (novel and unobvious) OVER EACH OTHER . . ." (MPEP § 802.01; emphasis original).

Applying the above standard, the restriction of the claims into the 10 groups as set forth in the Restriction Requirement is clearly improper. Using Group I/II (claims 1-10) and Group III/IV (claims 11-20) as an example, the claims are clearly not independent or distinct as to warrant a restriction. Rather, methods claimed in these two groups of claims recite essentially the same steps. Because of their identical or similar claim limitations, they are also unlikely to be patentable over each other. Instead, between these two groups of claims, patentability of one group would necessarily indicate the patentability of the other. As to burden on the Examiner, the subject matter encompassed by Group I/II claims are not in different art classes or subclasses from that encompassed by Groups III/IV claims. Because these two claims recite essentially the same claim elements, all prior art relevant to Group I/II claims should reasonably have been encompassed by the search already performed with respect to Group III/IV. For these reasons, the restriction between Group I/II and Group III/IV claims is improper.

Similarly, the other groups of claims (Groups V-X) recite similar claim elements on which patentability of the claims reside. These claims are not so independent or distinct as to warrant restrictions among themselves, or between each of these groups and one of Groups I-IV.

Therefore, withdrawal of the restriction among these ten groups of claims is respectfully requested.

II. Improper restriction of patent application that include generic claims

Applicants note that among the genes recited in the claims, an election of species requirement might be proper, but a restriction requirement as set forth in the Office Action is clearly erroneous. The basis for restriction practice is set forth in 37 CFR §§ 1.141-1.146 and the corresponding sections of the MPEP (MPEP §§ 803, 806, and 809). According to 37 CFR § 1.141, an applicant may not claim two or more independent and distinct inventions in a single application "except that more than one species of an invention . . . may be specifically claimed in different claims in one national application, provided the application also includes an allowable claim generic to all the claimed species and all the claims to species in excess of one are written in dependent form or otherwise include all the limitations of the generic claim" (emphasis added). Thus, "[w]here an application contains a generic claim for all of the disclosed species, a restriction usually is not proper." *R2 Medical Systems, Inc. v. Katecho, Inc.*, 931 F. Supp. 1397, 1436, n. 16, n. 17 (N.D. Ill. 1996).

The procedure for handling applications that include generic claims is set forth in 37 CFR § 1.146. This rule provides that "[i]n the first action on an application containing a generic claim to a generic invention (genus) and claims to more than one patentably distinct species embraced thereby, the examiner may require the applicant in the reply to that action to elect a species of his or her invention to which his or her claim will be restricted if no claim to the genus is found to be allowable." As stated in MPEP § 809.02(a), "[u]pon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141." Thus, where generic claims are present, an applicant can be required to elect a species for initial examination, but the generic claims are still subject to examination to determine whether such generic claims are allowable.

Applicants respectfully note that the required procedure noted above is not being followed in the instant Restriction Requirement. Claims 1, 11, 21, 32, 44, 54, and 58 are each proper generic claims within the requirements set forth in 37 CFR § 1.141. These claims satisfy the definition of a generic claim as set forth in MPEP § 806.04(d), in that none of these generic claims includes limitations that are not present in all claims that depend from the respective generic claims. Therefore, although the generic claims recite multiple gene species, the restriction requirement as rendered is improper.

III. Improper to split single claim into multiple inventions

The subject Restriction Requirement is also improper because it splits a single claim into multiple inventions. For example, claims 1, 11, 21, 32, 44, 54, and 58 are each split into $4.5x10^{105}$ inventions by the restriction requirement. As such, the restriction requirement is improper as a matter of law. The courts have long held that the section of the patent statute that authorizes restriction practice, *i.e.*, 35 U.S.C. 121, provides no legal authority to impose a rejection on a single claim, even if the claim presents multiple independently patentable inventions. *See, In re Weber*, 198 USPQ 328, 331 (CCPA 1978); *In re Haas*, 179 USPQ 623, 624-625 (*In re Haas I*) (CCPA 1973) and *In re Haas* 198 USPQ 334-337 (*In re Haas II*) (CCPA 1978). As stated in *In re Weber*:

> "The discretionary power to limit one applicant to one invention is no excuse at all for refusing to examine a broad generic claim—no matter how broad, which means **no matter how many independently patentable inventions may fall within it**." 198 USPQ 328 at 334 (emphasis added).

In a case such as the subject application, where a claim is generic, a restriction requirement is tantamount to a rejection of the claim. The CCPA made this point very clear in *In re Haas I*:

> "We find that the action taken by the examiner did in fact amount to a rejection. . . . Those claims were withdrawn from consideration not only in this application but prospectively in any subsequent application

> because of their content. In effect there had been a denial of patentability of the claims. Presumably only by dividing the subject matter into separate, and thus different, claims in plural applications could an examination of the patentability of their subject matter be obtained." 179 USPQ at 625.

If the instant restriction requirement is allowed to stand, Applicants will never be accorded "the basic right of the applicant to claim his invention as he chooses." *In re Weber*, 198 USPQ at 331. In *In re Weber*, the CCPA stated that "[a]s a general proposition, an applicant has a right to have **each** claim examined on the merits" (198 USPQ at 331, emphasis in original). The Court went on to state that:

> "If . . . a single claim is required to be divided up and presented in different applications, that claim would never be considered on its merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification." 198 USPQ at 331.

Even if Applicants were to able to file $4.5x10^{105}$ divisional applications to obtain coverage for each of the possible combinations of genes specified in the claims, as was apparently required by the Office Action, they would not have the opportunity to have their broader claims examined. The claims of the divisional applications would be limited to the particular combination set forth in the respective groups. In effect, the restriction requirement is reading into Applicants' independent claims certain limitations that are not present in the claims as filed. These independent claims would never be considered under the current restriction requirement. Rather, only the species claims to be pursued in the divisional applications would be examined.

For all the reasons stated above, Applicants respectfully request that the instant restriction requi rement be withdrawn and treated as though it were a species election under the procedure set forth in MPEP 809.02(a). Pursuant to 37 C.F.R. § 1.144, Applicants reserve the right to petition for review of the restriction requirement at any time prior to appeal. Applicants